REMARKS

State of the Claims

Claims 1-44 are pending. Claim 6 has been canceled without prejudice. Claims 1-5 and 7-44 remain.

35 U.S.C. § 112 Rejection

Claim 6 stands rejected under 35 U.S.C. § 112, first paragraph, because the Examiner asserts that the specification, while being enabling for the addition of an "asparagines-reducing enzyme" (i.e., asparaginase), does not reasonably provide enablement for any random method reaction of "reducing the level of asparagines" in corn-based food material.

Applicants have canceled Claim 6 without prejudice thus obviating the Examiner's rejection.

Claims 1-5, 7-10, 11-30 and 41-44 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention.

The Examiner states that the term "reduced" in Claims 11-30 and 41-44 is a relative term and therefore renders the claims indefinite. The Examiner further states that the term 'reduced' "is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention."

Applicants respectfully disagree with the Examiner's assertions. First, Applicants point out that the claims alone do not have to define the term "reduced". Rather, the specification can provide the proper basis for definition of any term used in the claim. Applicants assert that the specification does in fact provide the proper definition and understanding of the term "reduced" as it relates both to asparagine-reduction and acrylamide-reduction.[1]

In addition, common usage of a term can provide definition for claim terms. For example, the term "reduced", in common usage, is defined as "to lessen in extent, amount, number, degree or price." The American Heritage Dictionary, 2nd Ed., Houghton Mifflin Company, Boston (1991). Such definition bolsters Applicants' use of the term in their specification since Applicants teach the reduction of the amount of acrylamide in corn-based food material in comparison to corn-based food material not treated for such acrylamide reduction.

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[1] Applicants' Specification, page 3, lines 10-12: "Accordingly, Applicants have further discovered that acrylamide formation in heated food products can be *reduced* by removing the asparagine or converting the asparagine in the food to another substance before cooking." [Emphasis added.]

Whether one skilled in the art looks to the specification or to common usage, it would be apparent to one skilled in the art that the term "reduced," as used in the presently rejected claims, means that the level of asparagine/acrylamide is less in treated corn-based food material, i.e., corn-based food material not exposed to asparagine-reducing enzymes. Thus, the term "reduced" means that the corn-based food material has been treated with an enzyme such that the level of asparagine/acrylamide is less than what it would be in untreated corn-based food material.

Applicants respectfully assert that one skilled in the art would understand that the use of the term "reduced" in the present claims describes the level of asparagine or acrylamide in treated corn-based food material as compared to the level present in untreated corn-based food material. Therefore, it is respectfully asserted that the term "reduced" in the presently rejected claims does indeed provide a standard for ascertaining the meaning, such that one skilled in the art would be reasonably apprised of the scope of the claimed invention.

As such, Applicants respectfully request reconsideration and allowance of Claims 1-5, 7-10, 11-30 and 41-44 over the Examiner's 35 U.S.C. § 112, second paragraph, rejection.

The Examiner also states that the term "asparagine-reducing enzyme" in Claims 1-5 and 7-10 may be misleading. Specifically, the Examiner states that asparagine is not an actual oxido-reductase class of enzymes but rather, belongs to the hydrolase class of enzymes. The Examiner continues by saying that "while Applicant presumably intends this term to broadly encompass any enzyme which reduces the amount of asparagine in the product, it is technically improper." Finally, the Examiner concludes by quoting Process Control Corp. v. HydReclaim Corp.,190 F.3d 1350 (Fed Cir. 1999) which says that where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term.

Applicants respectfully traverse this rejection. The term "reducing," as used within the phrase "asparagine-reducing enzyme," refers not to a class of enzymes, but rather to their functionality. Moreover, contrary to the Examiner's contention, the term "asparagine-reducing enzyme" is fully defined in the present specification. Specifically, in the present specification, both of the foregoing concerns are addressed as the term "asparagine-reducing enzyme" is defined as "any enzyme capable of reducing the *level* of asparagine in corn-based food material."[2] [Emphasis added.] There is no mention of enzyme class or reduction reactions, such that one skilled in the art would be misled as to the meaning of the term as the Examiner claims. Indeed, in light of the foregoing definitions, Applicants respectfully assert that

"asparagine-reducing enzyme" is clearly defined in the present specification such that one skilled in the art would understand that "asparagine-reducing" relates to the level of asparagine rather than the class of the enzyme described therein. For these reasons, Applicants respectfully traverse the Examiner's rejection of the use of the term "asparagine-reducing enzyme" under the second paragraph of §112.

Therefore, Applicants respectfully request reconsideration and allowance of Claims 1-5 and 7-10 over the Examiner's 35 U.S.C. § 112, second paragraph, rejection.

In Claim 5, the Examiner states that the method generally recites "a food material" but does not indicate that the material is a corn-based food material, as stated in the preamble.

Applicants have amended Claim 5 so that the phrase "a food material" is properly modified by the phrase "corn-based" thus removing all ambiguity.

Applicants therefore believe that Claim 5 should now be held allowable over the Examiner's 35 U.S.C. § 112, second paragraph, rejection.

Claims 42 and 44 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Examiner states that the term "low" used herein is a relative term which renders the claims indefinite. The Examiner states that the term "low" is not defined by the claims, that the specification does not provide a standard for ascertaining the requisite degree, and that one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Lastly, the Examiner states that there is no standard or original amount of acrylamide provided in the specification such that one skilled in the art (or a consumer of the claimed article) would be apprised of what constituted a "low" amount of acrylamide within the article.

Applicants respectfully disagree with the Examiner. First, Applicants point out that Claims 42 and 44 are article of commerce claims and as such claim the communication of a "low" level of acrylamide in the corn-based food material. Such a communication is amply supported by the specification.[3]

In Claims 42 and 44, the message informs the consumer that the corn-based food material are low in acrylamide. Applicants assert that one of skill in the art would, by the claims themselves and from Applicants' specification, understand that the invention is an article of commerce that has as part of its packaging or advertising a message communicating the "low"-ness of acrylamide and the reduction thereof. Applicants further assert that a consumer reading this message would understand what this

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[2] Id. at page 4, lines 11-12.
[3] Id. at page 16, lines 10-35.

"low"-ness is intended to convey without, as the Examiner puts it, providing "a standard for ascertaining the requisite degree" of the "low"-ness of the acrylamide.

Furthermore, Applicants respectfully point out that the term "low" as used in claims 42 and 44 is simply a word on a label, and thus, there is no definiteness issue surrounding its use in this context. A label either displays the term "low," or a similar term, or it doesn't. Therefore, because the presently rejected claim relates only to the labeling of the product, rather than the potato products, it is irrelevant what the term "low" actually means in these claims. (It will be left to the appropriate regulatory body to determine whether the use of the term "low" on a label, as claimed herein, is proper).

Thus, Applicants respectfully assert that the Examiner's rejection of Claims 42 and 44 should be obviated and allowed to issue over the Examiner's 35 U.S.C. § 112, second paragraph, rejection.

35 U.S.C. § 103 Rejection

Claims 1-44 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Elder, et al. (U.S. Patent Application No. 2004/0058054--hereinafter, Elder '054). Claim 6 has been canceled without prejudice. Claims 1-5 and 7-44 remain.

The Examiner states that Elder '054 discloses "a method for reducing the amount of acrylamide in thermally processed foods". The Examiner points out that Elder '054 discloses contacting asparagine with the enzyme asparaginase. The Examiner further notes that Elder '054 provides in Example 5 proof that acrylamide reduction was reduced by more than 99.9%. The Examiner then sums up by stating that it would have been obvious to one of ordinary skill in the art to have added an asparaginase enzyme to corn-based food material prior to heating/cooking in order to reduce the level of asparagine within the corn-based food material.

The Examiner bears the burden of factually supporting any prima facie conclusion of obviousness. In determining the differences between the cited art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. See Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fe. Cir. 1983). Distilling the invention down to the "gist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." See W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983). Inventors of unobvious compositions, such as those of the present invention, enjoy a *presumption* of non-obviousness, which must then be overcome by the Examiner establishing a case of prima facie obviousness by the appropriate standard. If the Examiner does not prove a prima facie case of unpatentability, then without more, the Applicant is entitled to grant of the patent. *See* In re Oetiker, 977 F.2d 1443.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all of the claim limitations.[4]

With regard to this obviousness rejection, Applicants respectfully disagree with the Examiner and assert that Elder '054 not only does not teach or suggest Applicants' invention but also fails to provide a reasonable expectation of success between its examples, particularly example no. 5, and the claimed subject matter of Elder '054, namely reducing the presence of acrylamide in thermally processed food. In so doing, Elder '054 has failed to appreciate the difficulty in adding or applying an asparagine-reducing enzyme to corn-based food material.

To begin, Applicants note that there are stark differences between 1) Applicants' corn-based food material and Elder's simple sugar and amino acid filled test tube and 2) reducing the levels of asparagine and/or acrylamide in corn-based food material versus that of simple sugar and amino acid. Looking carefully at the Example Nos. 1-5 of Elder '054, one immediately understands that the reduction of either asparagine or acrylamide is **never achieved in food**, or any edible, complex multi-celled structure like corn-based food material. Rather, Elder '054 merely adds simple sugar to amino acid in test vials, heats the materials, adds asparaginase and then records, essentially, the reaction of asparaginase to the sugar/amino acid combination in the way of reduced levels of acrylamide formed. More specifically, Elder '054 only shows the reduction of acrylamide in one example, namely, Example No. 5.

In Example No. 5, glucose is added to asparagine and then heated to form acrylamide. Next, asparaginase is added to the glucose/asparagine mix. Subsequently, the acrylamide levels are measured and compared with two untreated controls. Although a reduction in acrylamide is shown, Applicants assert that such experiments, without more, do not provide a reasonable expectation of success that one of skill in the art reading Elder '054 would be able to reduce asparagine/acrylamide **in food**, or any edible, complex multi-celled structure like corn-based food material. Elder's Example No. 5 is limited only to test vials with ingredients that cannot fairly be said to be corn-based food material or any other kind of food. Rather, the components glucose and asparagine represent the most basic building blocks of many foods but lack the complex structure of most foods, e.g., Applicants' corn-based food material.

Furthermore, Elder '054 only mentions that asparaginase can be used to come into "contact" with the simple sugar/amino acid combination. Other than putting asparaginase in the test tubes of Example No. 5, the nature of this "contact" is never explained, defined or taught. Applicants' "contact" of their

[4] In re Vaeck, 947 F. 2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

asparagine-reducing enzyme is much more robust and definitive.[5] Applicants' disclosure is extensive and details their break-through ability of adding an asparagine-reducing enzyme to corn-based food material to reduce asparagine levels in the beans. Such detailed addition is necessary because of complex multi-celled structures like corn-based food material. One of skill in the art knows that in order to penetrate the cell walls of, say, corn-based food material, much work and energy must be applied in order to reach the interior of the cells of the corn-based food material; i.e., the cite where asparagine is produced. Such difficulty is not appreciated by Elder '054.

As such Elder '054 has not taught or suggested Applicants' invention and furthermore has merely made unsubstantiated assertions of acrylamide reduction in food based on examples that do not teach or suggest the reduction of asparagine/acrylamide in corn-based food material or any other kind of food.

Applicants therefore respectfully request reconsideration and allowance of Claims 1-5 and 7-44 over the Examiner's 35 U.S.C. § 103(a) rejection in view of Elder '054.

With regard to Claims 41-44 the Examiner states that it would have been obvious to one of ordinary skill in the art to have packaged and appropriately labeled the food products produced by Elder '054. Such packaging techniques, notes the Examiner, were well known in the art. The Examiner further states that if Applicants' product claims are found to be allowable, then the article container claims 17-18 would also be allowable.

Applicants respectfully disagree with the Examiner's assertions. Applicants' respectfully assert that the Examiner is using the wrong test for obviousness. The test is whether the reference itself , herein Elder '054, or knowledge generally available to one of skill in the art teaches or suggests Applicants' invention. Applicants assert that neither condition has been met.

First, nothing in Elder '054 teaches or suggests an article of commerce that communicates the reduction or lowness of acrylamide in Applicants' corn-based food material or any other kind of food. As noted extensively herein, Elder '054 does not itself teach the reduction of acrylamide in corn-based food material or of any other food, but merely a reaction of an enzyme with asparagine and simple sugar in a test vial.

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[5] Applicants' Specification at page 5, lines 32-35 to page 6, lines 1-2: "The enzyme may be added to the corn-based food material in any suitable form. For instance, the enzyme may be added as a powder or in the form of a solution. Furthermore, the enzyme may be added to the corn-based food material in any suitable manner, such as directly (for example, sprinkled, poured, or sprayed on the corn-based food material, or the corn-based food material can be soaked in an enzyme solution) or indirectly. [Applicants' disclosure is replete with this kind of detailed teaching.]

Second, Applicants assert that one of skill in the art would not have been led to produce an article of commerce that communicates the reduction of acrylamide in corn-based food material or any other kind of food. Heretofore, the ability to reduce acrylamide in edible structures producing asparagine has never been accomplished until Applicants accomplished this reduction. Thus, there was no knowledge generally held available to one of skill in the art that such a claim, i.e., the reduction or lowness of acrylamide in food, was possible or even desired. Applicants point out that they claim an article of commerce having a message informing a consumer that the product has a reduced level of acrylamide. Applicants are not claiming a generic message or merely words on a package which is within the knowledge of one of ordinary skill in the art. Rather, Applicants' message is specific to a heretofore unobtainable function by any one of skill in the art save Applicants. Such a message is therefore not within the knowledge of one of ordinary skill in the art.

Thus, Applicants respectfully request reconsideration and allowance of Claims 41 and 44 over the Examiner's 35 U.S.C. § 103(a) rejection in view of Elder '054.

Double Patenting - Non-Statutory

Claims 41-44 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-12 of co-pending Application No. 10/606,260.

Applicants respectfully traverse these rejections. Applicants submit that the Examiner has failed to provide sufficient basis for asserting that the cited claims of U.S. Patent Application No. 10/606,260 teach or suggest the claims of the present application which are directed to reducing asparagines or acrylamide in food. Accordingly, it is respectfully requested that the obviousness-type double patenting rejections be withdrawn.

Claims 1-44 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 and 42-50 of co-pending Application No. 10/606,137. Claim 6 has been canceled without prejudice. Claims 1-5 and 7-44 remain.

Applicants respectfully traverse these rejections. Applicants submit that the Examiner has failed to provide sufficient basis for asserting that the cited claims of U.S. Patent Application No. 10/606,137 teach or suggest the claims of the present application which are directed to reducing asparagine or acrylamide in food. Accordingly, it is respectfully requested that the obviousness-type double patenting rejections be withdrawn.

Claims 11-44 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-14 of co-pending Application No. 10/603,978.

Applicants respectfully traverse these rejections. Applicants submit that the Examiner has failed to provide sufficient basis for asserting that the cited claims of U.S. Patent Application No. 10/603,978 teach or suggest the claims of the present application which are directed to reducing asparagines or acrylamide in food. Accordingly, it is respectfully requested that the obviousness-type double patenting rejections be withdrawn.

SUMMARY

The rejections in the Office Action have been discussed and, Applicants believe, the proper discussions and/or amendments have been set forth to address the rejection.

In light of both the amendments and the discussions contained herein, Applicants respectfully request reconsideration of the rejection and its withdrawal.

Issuance of a Notice of Allowance at an early date is earnestly solicited.

Respectfully submitted,

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